PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

POPP

Examiner: L. Channavajjala

Serial No.: 10/617,191

Art Unit: 1615

Filed: July 11, 2003

For: **TOPICAL FORMULATIONS FOR TREATMENT OF SKIN DISORDERS**

Appendix A

Please amend the claims according to the following "marked-up" copy of the claims:

1. (Currently Amended) A topical composition for treating a skin disorder or condition, which comprises:

a storage-stable mixture of a benzoyl peroxide dispersion, clindamycin or a pharmaceutically acceptable salt or ester thereof, and a pharmaceutically acceptable carrier prepared by a process of mixing the benzoyl peroxide dispersion and the clindamycin or a pharmaceutically acceptable salt or ester thereof such that the composition has a viscosity lower than the benzoyl peroxide dispersion's viscosity before mixing,

wherein the composition has a final pH of about 4.5 to about 5, and wherein the composition maintains at least about 88% by weight of the clindamycin present in the composition prepared by the process for a period of at least 2 years at a temperature of about 6° C or less ~~has a viscosity lower than the viscosity of the benzoyl peroxide dispersion before mixing~~.

2. (Original) The composition of claim 1, wherein said composition is formulated for once-per-day administration.

3. (Original) The composition of claim 2, wherein said once-per-day administration occurs in the A.M.

4. (Original) The composition of claim 1, wherein said composition is formulated for twice-per-day administration.

5. (Original) The composition of claim 1, wherein said composition has a final pH of about 4.6 to about 4.8.

6. (Original) The composition of claim 1, wherein said dispersion is selected from the group consisting of a gel, cream, lotion, suspension, emulsion, ointment, foam, and mixtures thereof.

7. (Original) The composition of claim 1, wherein said composition is stored at a temperature of less than about 30 ^{O}C.

8. (Original) The composition of claim 1, wherein said composition is storage-stable for commercial purposes.

9. (Original) The composition of claim 1, wherein said composition has a final viscosity of about 50,000 to about 200,000 centipoises.

10. (Original) The composition of claim 9, wherein said composition has a final viscosity of about 100,000 to about 200,000 centipoises.

11. (Original) The composition of claim 1, wherein said benzoyl peroxide dispersion has a viscosity of about 60,000 to about 250,000 centipoises.

12. (Original) The composition of claim 11, wherein said benzoyl peroxide dispersion has a viscosity of about 110,000 to about 220,000 centipoises.

13. (Original) The composition of claim 1, wherein said benzoyl peroxide is about 65% to about 80% pure.

14. (Original) The composition of claim 1, wherein said mixture comprises about 1% to about 20% by weight percent benzoyl peroxide.

15. (Original) The composition of claim 14, wherein said mixture comprises about 2.25% to about 12.5% by weight benzoyl peroxide.

16. (Original) The composition of claim 1, wherein said composition further contains inactive ingredients selected from the group consisting of carbomer, disodium monolauryl sulfosuccinate, disodium EDTA, methyl paraben, poloxamer, glycerin, dimethicone, hydrated silica, sodium hydroxide, purified water, and mixtures thereof.

17. (Currently Amended) A method for treating a skin disorder or condition in a patient comprising topically administering to a patient in need thereof ~~a~~ the topical composition of claim 1 in an amount effective to treat said skin disorder~~, wherein said composition comprises:~~

~~a storage-stable mixture of a benzoyl peroxide dispersion, clindamycin or a pharmaceutically acceptable salt or ester thereof, and a pharmaceutically acceptable carrier,~~

~~wherein the composition has a final pH of about 4.5 to about 5, and wherein the composition has a viscosity lower than the viscosity of the benzoyl peroxide dispersion before mixing~~.

18. (Original) The method of claim 17, wherein said skin disorder or condition includes a microbial infection.

19. (Original) The method of claim 18, wherein said microbial infection is caused by bacteria selected from the group consisting of gram-positive bacteria, gram-negative bacteria, and mixtures thereof.

20. (Original) The method of claim 19, wherein said bacteria is selected from the group consisting of *P. acnes, Strep. Pyogenes, E. coli, Pseudonomas originosa, Staph. Aureus*, and mixtures thereof.

21. (Original) The method of claim 17, wherein said skin disorder or condition includes an inflammation of tissue.

22. (Original) The method of claim 21, wherein said skin disorder is selected from the group consisting of acne, impetigo, rosacea, atopic dermatitis, secondary skin infections, and mixtures thereof.

23. (Original) The method of claim 17, wherein said patient is between the ages of 2 and 45.

24. (Original) The method of claim 23, wherein said patient is between the ages of 10 and 35.

25. (Original) The method of claim 24, wherein said patient is between the ages of 12 and 25.

26. (Currently Amended) A process for preparing a storage-stable topical

composition for treating for a skin disorder or condition, which comprises the steps of:

a) forming at a temperature of about 15 to about 25 ^{O}C a benzoyl peroxide intermediate dispersion having between about 5.9% and about 7.2% benzoyl peroxide and having a viscosity of about 60,000 to about 250,000 centipoises;

b) forming at a temperature of about 15 to about 25 ^{O}C a clindamycin intermediate solution sufficient to yield a composition which contains between about 0.5% and about 1.5% by weight clindamycin active in the final product; and

c) mixing said benzoyl peroxide intermediate dispersion and said clindamycin intermediate solution under conditions sufficient to yield a benzoyl peroxide and clindamycin mixture having final pH of between about 4.5 to about 5.0,

wherein said mixture has a viscosity lower than the viscosity of the benzoyl peroxide intermediate dispersion, wherein the viscosity of the mixture is of about 50,000 to about 200,000 centiposies, and wherein said composition comprises sufficient inactive ingredients to provide storage stability and effectiveness for a treatment period.

27. (Original) The process of claim 26, wherein said process results in a composition having benzoyl peroxide impurities of not more than about 0.01% by weight.

28. (Original) The process of claim 26, wherein said process results in a composition having clindamycin degradates of not more than about 0.02% by weight.

29. (Original) The process of claim 26, wherein said process results in a composition

having benzoyl peroxide impurities of not more than about 0.01% by weight and clindamycin degradates of not more than about 0.02% by weight.

30. (Original) The process of claim 26, wherein said mixture has a final pH of between about 4.6 to about 4.8.

31. (Original) The process of claim 26, wherein said composition has less water by weight as compared to a topical formulation having one of benzoyl peroxide or clindamycin but not both.

32. (Original) A dermatological composition for topical treatment of skin disorders, which comprises:

a composition produced according to the process of claim 26, having a standard deviation of amount of benzoyl peroxide present within $\pm$ 0.07 and a standard deviation of amount of clindamycin present within $\pm$ 0.015.

33. (Original) The composition of claim 32, wherein said composition is selected from the group consisting of a gel, cream, lotion, suspension, emulsion, ointment, foam, and mixtures thereof.

34. (Original) The composition of claim 33, wherein said composition is a gel.

35. (Original) The composition of claim 1, wherein said composition is stored in a substantially non-reactive laminated package to enhance stability of the package.

36. (New) A topical composition for treating a skin disorder or condition, which comprises:

a storage-stable mixture of a benzoyl peroxide dispersion, clindamycin or a pharmaceutically acceptable salt or ester thereof, and a pharmaceutically acceptable carrier prepared by a process of mixing the benzoyl peroxide dispersion and the clindamycin or a pharmaceutically acceptable salt or ester thereof such that the composition has a viscosity lower than the benzoyl peroxide dispersion's viscosity before mixing,

wherein the composition has a final pH of about 4.5 to about 5, and wherein the composition maintains at least about 96% by weight of the benzoyl peroxide and at least about 89% by weight of the clindamycin present in the composition prepared by the process for a period of at least 3 months at a temperature of about 25^{O} C or less.

37. (New) A topical composition for treating a skin disorder or condition, which comprises:

a storage-stable mixture of a benzoyl peroxide dispersion, clindamycin or a pharmaceutically acceptable salt or ester thereof, and a pharmaceutically acceptable carrier prepared by a process of mixing the benzoyl peroxide dispersion and the clindamycin or a pharmaceutically acceptable salt or ester thereof such that the

composition has a viscosity lower than the benzoyl peroxide dispersion's viscosity before mixing,

wherein the composition has a final pH of about 4.5 to about 5.